

We claim:

1. A solid pharmaceutical dosage form which comprises a solid dispersion of at least one HIV protease inhibitor and at least one pharmaceutically acceptable water-soluble polymer and at least one pharmaceutically acceptable surfactant.
2. The dosage form of claim 1, wherein said pharmaceutically acceptable water-soluble polymer has a Tg of at least about 50 °C.
3. The dosage form of claim 1 comprising a glassy solution or solid solution of said HIV protease inhibitor.
4. The dosage form of claim 1, wherein said pharmaceutically acceptable surfactant has an HLB value of from about 4 to about 10.
5. The dosage form of claim 1, wherein said pharmaceutically acceptable surfactant is a combination of at least one pharmaceutically acceptable surfactant having an HLB value of from about 4 to about 10 and at least one further pharmaceutically acceptable surfactant.
6. The dosage form of Claim 1 wherein said pharmaceutically acceptable surfactant is a sorbitan fatty acid ester.
7. The dosage form of Claim 1 which comprises, relative to the weight of the dosage form, from about 5 to about 30 % by weight of said HIV protease inhibitor, from about 50 to about 85 % by weight of said water-soluble polymer, from about 2 to about 20 % by weight of said surfactant, and from about 0 to about 15 % by weight of additives.
8. The dosage form of claim 1, wherein said HIV protease inhibitor is selected from the group consisting of: (2S,3S,5S)-5-(N-(N-methyl-N-((2-isopropyl-4-thiazolyl)-methyl)amino)carbonyl)-L-valinyl)amino-2-(N-((5-thiazolyl)methoxy-carbonyl)-amino)-amino-1,6-diphenyl-3hydroxyhexane (ritonavir);

(2S,3S,5S)-2-(2,6-Dimethylphenoxyacetyl)amino-3-hydroxy-5-[2S-(1-tetrahydro-pyrimid-2-onyl)-3-methylbutanoyl]-amino-1,6-diphenylhexane (ABT-378; lopinavir); N-(2(R)-hydroxy-1(S)-indanyl)-2(R)-phenylmethyl-4(S)-hydroxy-5-(1-(4-(3-pyridyl-methyl)-2(S)-N'-(t-butylcarboxamido)-piperazinyl))-pentaneamide (indinavir); N-tert-butyl-decahydro-2-[2(R)-hydroxy-4-phenyl-3(S)-[[N-(2-quinolylcarbonyl)-L-asparaginyl]amino]butyl]-4aS,8aS)-isoquinoline-3(S)-carboxamide (saquinavir); 5(S)-Boc-amino-4(S)-hydroxy-6-phenyl-2(R)phenylmethylhexanoyl-(L)-Val-(L)-Phe-morpholin-4-ylamide;

1-Naphthoxyacetyl-beta-methylthio-Ala-(2S,3S)-3-amino-2-hydroxy-4-butanoyl-1,3-thiazolidine-4-t-butylamide;

5-isoquinolinoxyacetyl-beta-methylthio-Ala-(2S,3S)-3-amino-2-hydroxy-4-butanoyl-1,3-thiazolidine-4-tbutylamide;

[1S-[1R-(R-),2S*]]-N¹ [3-[[[(1,1-dimethylethyl)amino]carbonyl](2-methylpropyl)amino]-2hydroxy-1-(phenylmethyl)propyl]-2-[(2-quinolinylcarbonyl)amino]-butanediamide;

amprenavir (VX-478);

DMP-323;

DMP-450 (Mozenavir);

AG1343 (nelfinavir);

atazanavir (BMS 232,632);

tipranavir;

palinavir;

TMC-114;

RO033-4649;

fosamprenavir (GW433908);

P-1946;

BMS 186,318;

SC-55389a;

L-756,423;

Tipranavir (PNU-140690);

BILA 1096 BS; and

U-140690, or any combinations thereof.

9. The dosage form of Claim 1 wherein said HIV protease inhibitor is (2S,3S,5S)-5-(N-(N-((N-methyl-N-((2-isopropyl-4-thiazolyl)methyl)amino)carbonyl)-L-valinyl)amino-2-(N-((5-thiazolyl)methoxy-carbonyl)-amino)amino-1,6-diphenyl-3-hydroxyhexane

(ritonavir).

10. The dosage form of Claim 9 which shows a dose-adjusted AUC, in dogs under non-fasting conditions, of ritonavir plasma concentration of at least about 9 µg.h/ml/100 mg.
11. The dosage form of Claim 1 wherein said HIV protease inhibitor is (2S,3S,5S)-2-(2,6-Dimethylphenoxyacetyl)-amino-3-hydroxy-5-[2S-(1-tetrahydropyrimid-2-onyl)-3-methyl-butanoyl]amino-1,6-diphenylhexane (lopinavir).
12. The dosage form of claim 11 which shows a dose-adjusted AUC, in dogs under non-fasting conditions, of lopinavir plasma concentration of at least about 20 µg.h/ml/100 mg.
13. The dosage form of claim 1 wherein said HIV protease inhibitor is a combination of (2S,3S,5S)-5-(N-(N-((N-methyl-N-((2-isopropyl-4-thiazolyl)methyl)amino)carbonyl)-L-valinyl)amino-2-(N-((5-thiazolyl)methoxy-carbonyl)-amino)-amino-1,6-diphenyl-3-hydroxyhexane (ritonavir) and (2S,3S,5S)-2-(2,6-Dimethylphenoxyacetyl)amino-3-hydroxy-5-[2S-(1-tetrahydropyrimid-2-onyl)-3-methylbutanoyl] amino-1,6-diphenylhexane (lopinavir).
14. The dosage form of claim 13 which shows a dose-adjusted AUC, in dogs under non-fasting conditions, of ritonavir plasma concentration of at least 9 about µg.h/ml/100 mg and a dose-adjusted AUC of lopinavir plasma concentration of at least about 20 µg.h/ml/100 mg.
15. The solid dosage form of Claim 1 wherein said water-soluble polymer has a Tg of from about 80 to about 180 °C.
16. The solid dosage form of Claim 1 wherein said water-soluble polymer is a homopolymer or copolymer of N-vinyl pyrrolidone.

17. The solid dosage form of Claim 1 wherein said water-soluble polymer is a copolymer of N-vinyl pyrrolidone and vinyl acetate.
18. The solid dosage form of Claim 1 containing at least one additive selected from flow regulators, disintegrants, bulking agents and lubricants.
19. The solid dosage form of Claim 1 which contains, upon storage for about 6 weeks at about 40 °C and about 75% humidity, at least about 98 % of the initial content of HIV protease inhibitor.
20. A method of preparing a solid dosage form of claim 1 which comprises:
 - i. preparing a homogeneous melt of said HIV protease inhibitor(s), said water-soluble polymer(s) and said surfactant(s), and
 - ii. allowing the melt to solidify to obtain a solid dispersion product.
21. The method of claim 20 additionally comprising grinding said solid dispersion product and compressing said solid dispersion product into a tablet.
22. A method of treating an HIV infection comprising administering the solid dosage form of claim 1 to a mammal in need of such treatment.